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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,637	08/01/2001	Ahmed Jehanli	01246.0134	2644

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Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, DC 20005-3315

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/918,637	JEHANLI ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12,14-16 and 19-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12,14-16 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Amendment Entry

1. The amendment filed October 8, 2004 has been entered. Claims 1-2,4,6, 8, 6, 12 and 16 have been amended. Claims 11, 13 and 17-18 have been cancelled. Claims 22-23 have been newly added. Claims 1-10, 12, 14-16, and 19-23 are under consideration in the office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 11 and13 under 35 U.S.C. 112, second paragraph;

b) The rejection of claims 1-2, 4-10, 12, 14-16, and 19-21 are rejected under 35 U.S.C. 112, second paragraph;

c) The rejection of claims 11 and 13 under 35 U.S.C. 103(a) as being unpatentable over Jehanli et al., (1996) and Cole et al., (US Patent 4,589,612) as applied to claims 1, 10 and 12 above, and further in view of Esser.

Response to Arguments

3. Applicant's arguments filed October 8, 2004 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The rejection of claim 3 under 35 U.S.C. 112, second paragraph is maintained because claim 3 still recites alternative limitations which are improperly expressed. Despite applicants amendments alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group recites members as being "selected from the group consisting of A, B and C". Another acceptable form recites "selected from 1, 2, 3, or 4." Applicant may correct this by amending the claim to recite the appropriate language. Claim 3 recites inappropriate claim language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The rejection of claims 1-3, 5-7, 9-10,12, 14-16 and 19-23 under 35 U.S.C. 103(a) as being unpatentable over Jehanli et al., (1996) in view of Cole et al., (US Patent 4,589,612) is maintained.

Claims 1-10, 12, 14-15 are drawn to a medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a drug conjugate and a second part that contains a labeled antibody and is adapted for receiving said fluid. The rejection was on the grounds that it would have been prima

facie obvious to modify the medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a drug conjugate and a second part that contains an enzyme labeled antibody and is adapted for receiving said fluid as taught by Jehanli et al., wherein no more than routine skill would have been required to incorporate the gold labeled antibody of Cole et al.

Applicants argue that Jehanli et al., do not teach qualitative or quantitative determination of a drug is achieved within at least 5 minutes but less than 30 minutes of the first part contacting the second part. However applicant is reminded that the claims are drawn to a kit. Thus a recitation of the intended use, such as determination of the drug with 5 to 30 minutes, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. There is no structural difference between the conjugate drug and label antibody of the prior art and those instantly claimed. Therefore the components described by Jehanli et al and Cole et al., teach the instantly claimed kit. Moreover, since the prior art structures are capable of performing the intended use, then they meet the claimed requirements.

Claims 16 and 19-21 are drawn to a method utilizing the medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a drug conjugate and a second part that contains a labeled antibody and is adapted for receiving said fluid. In claims drawn to a process of using, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA

1963). However there is no structural difference between the conjugate drug and label antibody of the prior art and those instantly claimed. The components described by Jehanli et al and Cole et al., teach the instantly claimed method. Moreover, since the prior art structures are capable of performing the intended use, then they meet the claimed requirements.

In response to applicant's arguments against the Jehanli et al., reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The prior art teaches that in immunoassay kits, once the antigen and antibody are mixed detection of color change can occur within 5 minutes. Moreover, Cole et al., teach in Example IV(a) that the drug conjugate and labeled antidrug antibody are mixed and incubated for 10 minutes, then vacuum filtered, dried and then visually inspected. In the same Example IV(e) Cole et al., teach a 5 minute incubation, followed by centrifugation, wash and visual observation. Example IV(f) and (g) teach a 10 minute incubation followed by pouring the samples onto a filter and then visual observing the results. Thereby teaching methods that allow for qualitative or quantitative determination of a drug is achieved within at least 5 minutes but less than 30 minutes of the first part contacting the second part. Therefore applicants' arguments are not persuasive.

Applicants' have failed to assert that the conjugates and antibodies of the prior art do not have the ability to achieve qualitative or quantitative determination of a drug

within at least 5 minutes but less than 30 minutes of the first part contacting the second part. Applicants' point to Jehanli et al., in support by stating the Jehanli et al., waited longer than 30 minutes to view its results, however this argument is not persuasive in view of the clear teaching of Cole et al. There is no teaching that the components of Jehanli et al., in view of Cole et al., do not have the same abilities, especially when considering that the components of the prior art are the same as those instantly claimed. Therefore the burden is on the applicant to present reason of authority for believing that the starting components i.e., the dug conjugate and labeled antibody, would take part in or affect the basic reaction and thus alter the nature or operability of the process and thus produce an unobvious method.

Thus applicants' arguments are not persuasive and the rejection is maintained.

6. The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Jehanli et al., (1996), and Cole et al., (US Patent 4,589,612) as applied to claim 1 above, and further in view of de Jaeger et al., (US Patent 4,837,168) is maintained for reasons already of record. The rejection was on the grounds that it would have been prima facie obvious to modify the medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a drug conjugate and a second part that contains a labeled antibody and is adapted for receiving said fluid as taught by Jehanli et al., and Cole et al., to include the colored latex particle label as taught by de Jaeger et al.

Applicants' asserts that because of the amendments, the rejection should be withdrawn. However as discussed above, the Jehanli et al., and Cole et al., teach that the components of the kit can achieve qualitative or quantitative determination of a drug within at least 5 minutes but less than 30 minutes of the first part contacting the second part. The prior art teaches the components of kit, therefore the prior art meets the limitation of the claim contrary to applicants assertions. Moreover, one would have a reasonable expectation of success by incorporating the antibody labeled with latex colored particles, into the kit of Jehanli et al., and Cole et al., who already teach using the labeled antibodies to qualitatively or quantitatively determine the presence of a drug in a biological fluid. Therefore the rejection is maintained since applicants' arguments are not persuasive.

7. The rejection of claims 8 and 22-23 under 35 U.S.C. 103(a) as being unpatentable over Jehanli et al., and Cole et al., as applied to claims 1-3 and 5-7 above, and further in view of Baker et al., is maintained. The rejection was on the grounds that it would have been prima facie obvious to modify the medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a drug conjugate and a second part that contains a labeled antibody and is adapted for receiving said fluid as taught by Jehanli et al., and Cole et al., wherein no more than routine skill would have been required to incorporate the lisinopril drug conjugate of Baker et al.

Contrary to applicants' belief that the amendment has obviated the rejection, the rejection is being maintained because the prior art teaches the components of the medical kit. Thus, one would have a reasonable expectation of success by incorporating the ACE drug lisinopril, when the prior art already teaches the determination of another ACE related drug which has similar functions into the device and method of Jehanli et al., and Cole et al., who already teach using the labeled antibodies to qualitatively or quantitatively determine the presence of a drug in a biological fluid within 5 to 30 minutes.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
December 23, 2004

LYNETTE R. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600